

REMARKS/ARGUMENTS

Applicants submit the aforementioned amendments and following remarks in response to the Final Office Action mailed October 18, 2007.

A petition for a three (3) month extension of time for responding to the Official Action is simultaneously filed herewith.

A Request For Continued Examination (RCE) is also being filed concurrently herewith.

Claims 5 and 6 are pending. Claims 5 and 6 have been amended. No new matter is added.

Reconsideration is respectfully requested in view of the above amendments and the following remarks.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 5 and 6 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. In response, Applicants have amended the claims as suggested by the Examiner. Therefore the rejections have been obviated and should be withdrawn.

Rejection under 35 U.S.C. § 102(a)

The Examiner rejected claims 1-5, 13-15, 17-18 under 35 U.S.C. § 102(a) as being anticipated by Margot et al. 1999. The Examiner states the HIV Drug Resistance Database discloses HIV reverse transcriptase mutation T386A in clinical isolates of MM-2121366851, MM-2149365661, MM-2152367401, MM-2536365721, MM-223966081, MM-3576366701 and MM-378368251. See Office Action, pages 3-4.

Applicants respectively transverse this rejection. Also, applicants respectively point out several discrepancies cited in the Office Action. First, claims 1-4, 7-10 have been canceled in the amendment filed August 2, 2007 and claims 13-15, 17-18 have never been submitted with the present application. The only claims currently under the examination are claims 5 and 6. Second, the reference of Margot et al. is published in 2002. Third, clinical isolates of MM-2121366851, MM-2152367401, MM-2536365721, and MM-378368251 are not listed in the database provided in the Office Action mailed February 7, 2007.

In view of the above discrepancies, applicants believe that the only claim that is rejected by the Examiner under 35 USC 102(a) is claim 5, therefore, applicant will address only claim 5 under U.S.C. § 102(a) in reference to Margot et al. and the HIV Drug Resistance Database.

With regard to the rejection to claim 5, the Examiner relies on (1) Margot et al. in teaching a method for evaluating the virological responses and mutational profiles in antiretroviral patients wherein reverse transcriptase and protease were analyzed, and (2) HIV Drug Resistance Database in disclosing the clinical isolates of MM-2149365661, MM-223966081, and MM-3576366701.

Margot et al. disclose an evaluation of virologic response and mutational profiles in antiretroviral patients after adding tenofovir to their existing regimens. See page 1227, Objective. Margot et al. do not teach a method of evaluating change in drug susceptibility in correlation with the mutation at position 386 in HIV reverse transcriptase. Specifically, Margot et al. do not teach the step (iv) which compares drug susceptibility in samples having mutation at the position 386 to those of samples having wild type amino acid at the same position. Subsequently, Margot et al. do not teach the step (v) which correlates the above mutation to the change in drug susceptibility.

The HIV Drug Resistance Database only discloses clinical isolates having mutations in HIV-1 reverse transcriptase.

The amended claim 5 is directed to a method of evaluating a change in HIV drug susceptibility by collecting samples from HIV-infected subjects, determining the presence of a mutation alanine at position 386 in HIV reverse transcriptase, comparing drug susceptibility of subjects having this mutation to those having a wild-type tyrosine at the same position, and correlating the mutation alanine at position 386 to the change in susceptibility to an HIV reverse transcriptase inhibitor.

With respect to a rejection under U.S.C. § 102(a), the law is clear in that all the limitations of a claim must be found within the four corners of a single reference. Neither Margot et al. nor the Database reference alone discloses all the limitations of claim 5. It is improper to combine these two references, Margot et al. and the HIV Drug Resistance Database, to make a rejection under U.S.C. § 102(a). Since each and every element as set

Application No.: 10/518,525

Docket No.: TIP 0016USPCT
EFS Filing Date: April 18, 2008

forth in claim 5 is not disclosed in either Margot et al. or the supplemental database, claim 5 is not anticipated by either of these two references alone. Accordingly, the rejection to claim 5 under 35 U.S.C. § 102(a) is improper and should be withdrawn. In view of the foregoing amendment and remarks, allowance of claims 5 and 6 is respectfully requested.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

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